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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,038	06/25/2003	Richard A. Anderson	WARF-0015	7983

7590
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11/08/2005

EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/606,038	Applicant(s) ANDERSON ET AL.	
	Examiner Ralph Gitomer	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of Group I, claims 1-3 in the reply filed on 10/3/05 is acknowledged. The traversal is on the ground(s) that the groups contain a common technical feature. This is not found persuasive because a common technical feature is not a criterion for restriction in US patent practice.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Caenepeel.

Caenepeel (US 2005/0125852 A1) with a 102(e) date of 5/9/2003, entitled "Novel Kinases" teaches in paragraph 76, lipid kinases such as PIPK's share minimal primary sequence similarity. Three residues are conserved among these enzymes including Lys-72 which binds the gamma phosphate of ATP, Asp-166 which is part of the HRDLK motif. In paragraph 194, the present invention is directed to methods of identifying compounds which modulate activity of kinase polypeptide compounds and determining whether the compound modifies activity of the kinase polypeptide. The activity in the presence of the test compound is compared to the activity in the absence of the test compound.

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All the features of the claim are taught by Caenepeel for the same function as claimed. Regarding the requirement that the method is performed in the presence of at least one selected protein, this reads on the kinase which is a selected protein.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Caenepeel in view of Schaller.

The claims differ from Caenepeel in that they specify the selected protein is Src and FAK.

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Schaller (Biochimica et Biophysica Acta) entitled "Biochemical Signals and Biological Responses Elected by the Focal Adhesion Kinase" teaches on page 7 the relation between FAK and Src where some residues are sites of phosphorylation by Src and some by FAK. These observations suggest that cell adhesion dependent tyrosine phosphorylation of FAK occurs in two phases, with and without Src.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to identify an agent that modulates PIPKIgamma661 as taught by Caenepeel with agents that modulate Src and FAK because Schaller teaches each of these enzymes participate in the same pathway and have related cellular functions. A compound that modulates either of Src or FAK would be expected to modulate PIPKIgamma661 as well because all are involved in regulating cell migration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The claims are directed to identifying an agent that modulates activity of PIPK γ 661 and the specification contemplates this in Fig. 2. However, there is no clearly disclosed data of specific agents that have been identified by the claimed method.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the first occurrence, each of the claimed acronyms should be spelled out. In claim 1 line 2, "the activity" lacks antecedent basis. In claim 1 line 4, "selected protein" does not recite how it was selected or for what. It is unclear in claim 3 if both Src and FAK are intended where the agent necessarily modulates activity of FAK.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Whyte (US 2004/0197792 A1) teaches kinases.

Bennett (US 2003/0114400 A1) teaches kinases.

Castelhano (6,465,495 B1) teaches kinases.

Cance (6,015,893) teaches kinases.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer
Primary Examiner
Art Unit 1655

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GROUP 1200